



PATENT

Customer Number: 22,852

Attorney Docket No: 03260.0047-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: )  
 )  
John Ernest SIMS ) Group Art Unit: 1646  
 )  
Serial No.: 09/612,921 ) Examiner: O. Chernyshev  
 )  
Filed: July 10, 2000 ) Confirmation No.: 9162  
 )  
For: IL-1 Delta DNA AND POLYPEPTIDES

**Mail Stop Appeal Brief - Patents**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**REPLY BRIEF UNDER 37 C.F.R. § 1.193**

In response to the Examiner's Answer dated October 14, 2004, Appellant submits the following remarks. This Reply Brief is due by December 14, 2004, and is timely filed.

**The Claims On Appeal Are Directed To Nucleic Acids**

The Examiner's characterization of the scope of the claims on appeal is incorrect. The Examiner states that the "claims are drawn to an isolated nucleic acid molecule and the protein encoded thereby of as yet undetermined function or biological significance." (Examiner's Answer at 4.) Although Appellant disagrees with the Examiner's characterization of the protein encoded by Appellant's claimed nucleic acid molecule, the claims on appeal are drawn to a nucleic acid molecule, and not to a protein. Accordingly, Appellant's arguments have focused on the utility and written description of the nucleic acid molecule in and of itself, irrespective of the protein that it encodes.

**The Examiner's Reasoning  
Is Contrary To Legal Precedent**

In the Examiner's Answer, the Examiner concludes that the use of an IL-1 delta nucleic acid molecule as a chromosomal marker does not constitute a specific and substantial credible utility. (Examiner's Answer at 9.) The Examiner's reasoning is that "DNA encoding IL-1 delta is not the only DNA that can be used to specifically identify chromosome 2" and the "use of the claimed nucleic acid of SEQ ID NO:3 to locate [the] 2q11-12 region of human

chromosome 2 would not make the polynucleotide of SEQ ID NO:3 any more 'specific' than virtually any other polynucleotide mapped to the same region." (*Id.* at 9 and 14.) The Examiner's reasoning is contrary to legal precedent.

Appellant's nucleic acid molecule encoding IL-1 delta need not be the only nucleic acid molecule useful for specifically identifying chromosome 2 or to locate the 2q11-12 region of human chromosome 2. *Carl Zeiss Stiftung v. Renishaw plc*, 20 U.S.P.Q.2d 1094, 1100 (1991) ("An invention need not be the best or the only way to accomplish a certain result . . ."). Appellant's nucleic acid molecule encoding IL-1 delta need only be useful to some extent and in some circumstances. *Id.* ("An invention . . . need only be useful to some extent and in certain applications.") Since the Examiner has not considered Appellant's invention using the appropriate legal standard, the Examiner has erroneously concluded that Appellant's nucleic acid molecule encoding IL-1 lacks utility. The Board should reverse that conclusion.

**The Examiner Concedes That Appellant's Claimed DNA Can Be Used In Currently Available Form To Detect Chromosomal Aberrations Of Chromosome 2**

The Examiner indicates that Appellant needs to provide evidence to associate IL-1 delta DNA with a particular

disease or condition. (Examiner's Answer at 12.) The Examiner's requirement is unnecessary for patentable utility. As Appellant's evidence has shown, one skilled in the art can use an IL-1 delta nucleic acid molecule to specifically identify chromosome 2, and more specifically, a particular region of chromosome 2 associated with chromosomal rearrangements found in the prior art. See Mu et al. In fact, the Examiner concedes that one skilled in the art would understand that "hybridization of the instant polynucleotides to [the] 2q11-12 chromosome region in [the] case of patients described in publications of Mu et al. could establish sequential aberrations . . . ."

(Examiner's Answer at 14.) The Examiner further concedes "that one skilled in the art could practice *in situ* hybridization using the instant claimed DNA, as well as any other DNA, without the need for additional research." (*Id.* at 15.) Consequently, the Examiner has conceded that Appellant's claimed nucleic acid molecule can be used in currently available form to detect chromosomal aberrations of chromosome 2, such as those that were previously described in the prior art.

This use of the claimed nucleic acid molecule is precisely what Appellant asserted as a utility in the specification. (Specification at 37: "to analyze

abnormalities associated with gene mapping to chromosome 2 . . . to distinguish conditions in which this marker is rearranged or deleted.") This specific and substantial use of Appellant's nucleic acid molecule fulfills the requirements for patentable utility.

**Detection of Chromosomal Aberrations  
Of Chromosome 2 Is A Real World  
Use for the Claimed Nucleic Acids**

In her Answer, the Examiner asks "if *in situ* hybridization using claimed SEQ ID NO:3 reveals certain rearrangement with human chromosome 2, what would that mean to the skilled artisan?" (Examiner's Answer at 14.) The answer to this question reveals the defect in the rejection. The answer is that, as demonstrated by Mu et al. the skilled artisan would understand that chromosome 2 was rearranged and that there was a correlation between that rearrangement and the clinical manifestations of the patient from which the DNA was taken. As was readily apparent to the authors of Mu et al., this result is an important real world use of nucleic acids that localize to this region of chromosome 2.

In the Examiner's Answer, the Examiner attempts to compare the instant situation with that in *Brenner v. Manson*. However, Appellant's claimed utility cannot be compared to the asserted utility in *Brenner*. As conceded

by the Examiner, Appellant's claimed nucleic acids can be used in currently available form for detecting chromosomal rearrangements of chromosome 2. This was not the case with the asserted utility in *Brenner*. As demonstrated by Mu et al. patients having chromosomal rearrangements on chromosome 2 were known to exist and to have various physical abnormalities. Thus, no further experiments would be necessary to use Appellant's claimed nucleic acids in the diagnosis of patients having rearrangements of chromosome 2, such as those described in Mu et al. Determination that a patient has a chromosomal rearrangement of chromosome 2 is a real world use in and of itself, which does not require any additional investigation. These facts distinguish the instant situation from that in *Brenner* and illustrate the real world utility of Appellant's claimed invention.

**Since Appellant Had Possession Of SEQ ID NO:3,  
Appellant Had Possession Of Fragments Of SEQ ID NO:3**

In the Examiner's Answer, the Examiner conceded that Appellant had possession of SEQ ID NO:3. (Examiner's Answer at 7.) The Examiner recognizes that claims 60 and 61 are directed to fragments of SEQ ID NO:3. (*Id.* at 6-7.) Nonetheless, the Examiner contends that "the claims are not limited to a polynucleotide with a specific nucleic acid

sequence" and that the "specification fails to describe the entire genus of nucleic acids, which are encompassed by these claims." (*Id.* at 7.)

First, Appellants note that claims 60 and 61 must comprise 30 or 60 contiguous amino acids of SEQ ID NO:3. Since Appellant **had possession of the entire IL-1 delta gene, SEQ ID NO:3**, Appellant must have had possession of fragments of this gene. Thus, the Examiner's position with respect to claims 60 and 61 is in error.

Second, the Court of Appeals for the Federal Circuit has found that written description of a genus of nucleic acids may be achieved by describing a representative number of nucleotide sequence within the scope of the genus or by describing common structural features of the genus. *Univ. of Cal. v. Eli Lilly & Co.*, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997) ("A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.")

Appellant has provided the **complete** nucleotide sequence of IL-1 delta. Thus, Appellant has provided the

nucleotide sequence of all of the members of the genus recited by claims 60 and 61. In addition, all of the nucleic acids encompassed by claims 60 and 61 must have the common structural feature of comprising 30 or 60 contiguous nucleotides of SEQ ID NO:3. Thus, all of the members of the claimed genus are structurally related to SEQ ID NO:3. Accordingly, claims 60 and 61 fulfill the written description requirement of 35 U.S.C. § 112, first paragraph, for a genus of nucleic acids as set forth in *Lilly*.

**The Nucleic Acids Of Claims  
65-67 Hybridize To SEQ ID NO:3**

The Examiner further recognized that claims 65-67 are directed to nucleic acid molecules that have at least 95%, 98%, or 99% sequence identity with SEQ ID NO:3. (Examiner's Answer at 7.) However, the Examiner appears to believe that these claims are "defined only by sequence identity." (*Id.* at 17.) The Examiner overlooks that claims 65-67 are dependent upon claim 62. Therefore, in addition to having sequence identity with SEQ ID NO:3, the nucleic acids of claims 65-67 must also hybridize to SEQ ID NO:3 under high stringency conditions. Together with high sequence identity with SEQ ID NO:3, the requirement for hybridization capability imposes both structural and

functional characteristics on the claimed nucleic acid molecules. When this combination of features of the nucleic acids of claims 65-67 is taken into account, it is evident that these claims fulfill the written description requirement of 35 U.S.C. § 112, first paragraph.

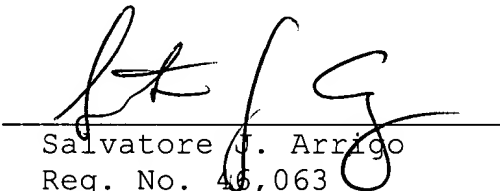
Please grant any extensions of time required to enter this Reply Brief and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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December 10, 2004

By: \_\_\_\_\_

  
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